

Remarks

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are pending in the subject application and read on the elected invention. Applicants acknowledge that claims 123, 125, 127, 128, 141-144, and 147-179 have been withdrawn from further consideration as being drawn to a non-elected invention. Accordingly, claims 1 and 115-179 (with claims 123, 125, 127, 128, 141-144, and 147-179 standing withdrawn) are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under the judicially created doctrine of “obviousness-type” double patenting over claims 51-55 of U.S. Patent No. 6,965,033. The Office Action states that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FB Pase inhibitor selected from the group of formula I or IA, and '033 claim 51 is drawn to a method of treating diabetes comprising administering a compound of formula I (wherein formula I is equivalent to the compounds of currently claimed formula I and IA). As the '033 patent uses the open language ‘comprising’ additional antidiabetic compounds can be administered including sulfonylureas such as glyburide.” Applicants respectfully assert that the claims are not obvious over the cited patent and traverse the rejection.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under the judicially created doctrine of “obviousness-type” double patenting over claim 1 of U.S. Patent No. 6,756,360. Applicants respectfully assert that the claims are not obvious over the cited patent. In this rejection, the Office Action argues that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FB Pase inhibitor selected from the group of formula I or IA, and '360 claim 1 is drawn to a pharmaceutical composition comprising an insulin sensitizer agent and an FB Pase inhibitor. In '360 claim 4 the FB Pase inhibitor is a compound selected from the formula I and IA wherein formula I and IA are identical to the formula I and IA of the current claim 1. Further glyburide is a known insulin sensitizer and secretagogue.” Applicants respectfully traverse the rejection.

As indicated previously, a double patenting rejection of the obviousness-type is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103” except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. 29 (C.C.P.A. 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985).

In the case of this rejection, it is, again, respectfully submitted that the cited patent and the rationale utilized for establishing the rejection fail to establish that the claimed composition is obvious over the claims of the ‘033 patent. Rather, the Office Action simply states that “[A]s the ‘033 patent uses the open language “comprising”[,] additional antidiabetic compounds can be administered including sulfonylureas such as glyburide”. Applicants respectfully submit that this simple assertion on the part of the Office Action fails to establish that the obviousness of the presently claimed invention over the claims cited in the ‘033 patent. Indeed, such a position is supported by the recently promulgated obviousness guidelines published by the Patent Office (see 72 Fed. Reg. 57526 (2007)) where it is stated “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*⁴¹ stated that “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’”⁴²” As previously indicated, such a rational underpinning of this obviousness-type double patenting rejection has not been provided. Accordingly, it is respectfully submitted that the requirements for establishing that the claimed invention is obvious over the claims of the cited patents is improper and withdrawal of the rejections is respectfully requested.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under 35 U.S.C. § 103(a) as obvious over Erion *et al.* (U.S. Patent No. 6,756,360) in view of Weber *et al.* (U.S. Patent No. 3,454,635). Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are also rejected under 35 U.S.C. § 103(a) as obvious over Jiang *et al.* (U.S. Patent No. 6,965,033) in view of Weber *et al.* (U.S. Patent

No. 3,454,635). The Office Action argues that the '033 patent and the '360 patent each teach the currently elected compound (Compound J) and its use for treating diabetes. The Office Action further argues that Weber *et al.* teach compositions comprising glyburide and their use in the treatment of diabetes. The Office Action then concludes that it would have been obvious to combine glyburide with the claimed FBPase inhibitors as each are useful in the treatment of diabetes (citing to *In re Kirkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980)). Applicants respectfully traverse.

While Applicants maintain that the obviousness-type double patenting rejections of record are not proper, Applicants also point out that the evidence of non-obviousness discussed herein with respect to the rejections set forth under 35 U.S.C. § 103(a) is also relevant to the double patenting rejections set forth in the Office Action. In the case of the instantly elected invention, Applicants respectfully submit that the combination of glyburide with the claimed FBPase inhibitors, such as Compound J, demonstrates unexpectedly superior results when used in the treatment of diabetes as compared to the administration of either compound alone. In Example X, for example, the combination of Compound J and glyburide was assessed for pharmacological activity in Zucker Diabetic Fatty rats (see pages 315-317). In this example, the combination treatment resulted in enhanced reduction in the area under the curve of blood glucose during the initial 4 hours post drug administration. Additionally, the combination treatment attenuated an increase in blood lactate levels that were observed in the compound J monotherapy group (see page 316, lines 30-31 and Figure 2 [page 317]). This result was more pronounced in chronic groups (page 317, lines 1-4). Further, Example Y indicates that the combination of glyburide and Compound J resulted in greater glucose lowering than either compound J or glyburide alone in chronic ZDF rats that were treated (see page 319). Applicants further submit that one skilled in the art would reasonably expect that compounds having core structures similar to those of Compound J (*e.g.*, such as those set forth in claims 115-132) would also be expected to demonstrate unexpectedly superior results as compared to individual monotherapy regimens. Thus, it is respectfully submitted that the claimed invention is not obvious in view of the cited combinations of references and reconsideration and withdrawal of the rejection is respectfully requested.

It is noted that the Office Action argues that Example Y is written in the future tense and that this indicates that the examples are prophetic and cannot supply evidence of unexpected results.

Applicants traverse this position. As noted in the previous response, Example X is directed to an analysis of compositions containing compound J and glyburide. In that example, data is presented that demonstrates that the combination of glyburide with the claimed FBPase inhibitors, such as Compound J, demonstrates unexpectedly superior results when used in the treatment of diabetes as compared to the administration of either compound alone. In Example X, the combination of Compound J and glyburide was assessed for pharmacologic activity in Zucker Diabetic Fatty rats (see pages 315-317) and the combination treatment resulted in enhanced reduction in the area under the curve of blood glucose during the initial 4 hours post drug administration. Additionally, the combination treatment attenuated an increase in blood lactate levels that were observed in the compound J monotherapy group (see page 316, lines 30-31 and Figure 2 [page 317]). This result was more pronounced in chronic groups (page 317, lines 1-4). Thus, contrary to the assertion made in the Office Action, data demonstrating unexpected results was presented that was not prophetic in nature and reconsideration of this data, in view of the comments presented herein, is respectfully requested.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Frank C. Eisenschenk". The signature is fluid and cursive, with a large, stylized "F" and "E".

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